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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/248,964	02/12/99	WUCHERPFENNIG	HAR-005

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EXAMINER
DECLoux, A

ART UNIT	PAPER NUMBER
1644	18

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/248,964

Applicant(s)

Wucherpennig

Examiner

DeCloux, Amy

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 7, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 103-113 is/are pending in the application.
- 4a) Of the above, claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 103-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14 20) ☐ Other:

DETAILED ACTION

1. Applicant's election WITH traverse of Group III (Claims 103-113) in Paper No. 17, filed 5-7-01, is acknowledged. Applicant's traversal is on the grounds that a search of any one of the claim groups would necessarily include a search in the classes and subclasses relevant to each of the other claim groups. However, because the products of each group are patentably distinct for the reasons of record and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, and would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper. The restriction is still deemed proper and is therefore made FINAL.
2. Claims 1-20 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
3. Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the PTO-948 form attached to Paper No. 15, mailed 3/12/01.
4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.
The oath or declaration is defective because: It claims priority to Provisional application 60/024007, which is incorrect. It appears priority should be claimed to Provisional Application Number 60/024077.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 103-113 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 103-113 are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "at least an extracellular domain of an MHC Class II alpha chain" as recited in line 4 of claim 103 and dependent claims 104-113) or for "at least an extracellular domain of an MHC Class II beta chain" as recited in line 7 of claim 103 and dependent claims 104-113). There is no written

description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**. It is noted that the instant specification discloses on page 6, lines 17-23, that said fusion protein comprises " at least an MHC class II binding domain of an MHC Class II alpha chain " and " at least an MHC class II binding domain of an MHC Class II beta chain ".

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 103-113 are rejected under 35 U.S.C. 102(e) as being anticipated by Schneck et al (US Patent #6,015,884) as evidenced by Janeway et al. (Fundamental Immunobiology, 3rd Edition, (1997).

'884 teaches divalent MHC peptide complexes which contain at least the extracellular domain of each of the MHC Class II chains, (see entire patent, especially Figure 1C, column 6, lines 20-25) are coupled to the dimerization domains of immunoglobulin heavy chain Ch1 constant region, or IgA, IgD, and IgG heavy chains (see entire patent especially column 10, lines 32-52 and column 12, lines 30-45) and can bind an MHC binding peptide (see entire patent, especially claims 1-6 and 9). An immunoglobulin hinge region flexible linker interposed between and covalently joining the CH1 heavy chain constant region (of IgG, IgD and IgA) and immunoglobulin Fc region, is linked by at least one disulfide bond, by virtue of the nature of an immunoglobulin, as evidenced by Janeway et al (Figures 3.2, 3.3, 3.4 and 3.21). '884 also teaches a multivalent class II MHC fusion protein comprising 5 pairs of MHC fusion proteins comprising IgM joined by disulfide bonds (see entire patent, especially column 9, lines 60-67) Therefore the referenced teachings anticipate the claimed invention.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
July 30, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644